Docket No.: NIH142.1CDV1

## INFORMATION DISCLOSURE STATEMENT

**Applicant** 

Gu et al.

App. No.

Unknown

Filed

Herewith

For

LIPOOLIGOSACCHARIDE-BASED VACCINE FOR PREVENTION OF MORAXELLA (BRANHAMELLA)

CATARRHALIS INFECTIONS IN

**HUMANS** 

Examiner

Unknown

Group Art Unit

Unknown

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

Enclosed is form PTO-1449 listing 74 references that are of record in U.S. patent application No. 09/610,034, filed July 5, 2000, which is the parent of this application, and is relied upon for an earlier filing date under 35 U.S.C. § 120. Copies of the references are not submitted pursuant to 37 C.F.R. § 1.98(d).

This Information Disclosure Statement is being filed with this application and no fee is required in accordance with 37 C.F.R. § 1.97(b)(1), (b)(2), or (b)(4).

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated:

12/5/03

By:

Nancy W. Vensko

Registration No. 36,298

Attorney of Record

Customer No. 20,995

(805) 547-5580

FORM PTO-1449

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

ATTY. DOCKET	NO.
NIH142.1CDV1	

APPLICATION NO. Unknown

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(USE SEVERAL SHEETS IF NECESSARY)

APPLICANT	
Gu, et al.	

FILING DATE GROUP
Herewith Unknown

U.S. PATENT DOCUMENTS							
EXAMINER INITIAL					FILING DATE (IF APPROPRIATE)		
	1.	5,013,661	05/07/91	Munford, et al			
	2.	5,334,379	08/02/94	Pillai, et al.	· .		
	3.	5,556,755	09/17/96	Murphy			
	4.	5,607,846	03/04/97	Murphy, et al.			
	5.	5,712,118	1/98	Murphy, T.F.			·
	6.	5,725,862	3/98	Murphy, T.F.			
	7.	6,207,157	3/01	Gu, et al.			

FOREIGN PATENT DOCUMENTS								
EXAMINER		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANS	LATION
INITIAL				·			YES	NO
	8.	98/53851	12/03/98	wo				

EXAMINER INITIAL		OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)
	9.	Ahmed, K., et al. (1991) Possible presence of a capsule in Branhamella catarrhalis. Microbiol. Immunol. 35: 361-366
	10.	Alaeus, A., et al. (1991) Branhamella catarrhalis septicemia in an immunocompetent adult. Scand. J. Infect. Dis 23: 115-116
	11.	Barenkamp, S.J. (1996) Immunization with high-molecular-weight adhesion proteins of nontypeable <i>Haemophilus influenzae</i> modifies experimental otitis media in chinchillas, Infect. Immun. 64: 1246-1251
	12.	Bhushan, R., et al. (1994) Molecular cloning and characterization of outer membrane protein E of <i>Moraxella</i> ( <i>Branhamella</i> ) catarrhalis. <u>J. Bacteriol.</u> 176:6636-6643
	13.	Blueston, C.D. (1986) Otitis media and sinusitis in children. Role of Branhamella catarrhalis. Drugs 31 (Suppl. 3): 132-141
	14.	Boyle, F.M., et al., (1991) Branhamella (Moraxella) catarrhalis: pathogenic significance in respiratory infections. Med. J. Aust. 154:592-596
	15.	Campagnari et al. (1990) Lipooligosaccharide epitopes shared among Gram- negative non-enteric mucosal pathogens. Microbial Pathogenesis 8:353-362
	16.	Campagnari, A.A., et al., (1994) Growth of Moraxella catarrhalis with human transferrin and lactoferrin: expression of iron-repressible proteins without siderophore production. Infect. Immun. 62:4909-4914
	17.	Catlin, B.W. (1990) Branhamella catarrhalis: an organism gaining respect as a pathogen. Clin, Microbiol. Rev. 3:293-320
	18.	Chapman, A.J., Jr., et al. (1985) Development of bactericidal antibody during Branhamella catarrhalis infection. <u>J. Infect. Dis.</u> 151:878-882
	19.	Chen, D. et al. (1996) Evaluation of Purified UspA from Moraxella Catarrhalis as a Vaccine in a Murine Model after Active Immunization Infection and Immunity, 64(6): 1900-1905
	20.	Christensen, J.J., et al., (1996) Serum antibody response to outer membrane proteins of Moraxella (Branhamella) catarrhalis in patients with bronchopulmonary infection. Clin. diagn. Lab. Immunol. 3:717-721
	21.	Cohen, D., et al. (1997) Double-blind vaccine-controlled randomised efficacy trial of an investigational Shigella sonnei conjugate vaccine in young adults. Lancet 340:155-159

EXAMINER	DATE CONSIDERED
*EXAMINER: INITIAL IF CITATION CONSIDERED, WHETHER OR NOT CITATION IS	S IN CONFORMANCE WITH MPEP 609; DRAW LINE THROUGH CITATION IF NOT

IN CONFORMANCE AND NOT CONSIDERED, INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT.

FORM PTO-1449

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

ATTY. DOCKET NO. NIH142.1CDV1

APPLICATION NO. Unknown

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(USE SEVERAL SHEETS IF NECESSARY)

APPLICANT Gu, et al.

FILING DATE Herewith GROUP Unknown

EXAMINER INITIAL		OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)
	22.	Doem, G.V. (1986) Branhamella catarrhalis - an emerging human pathogen. Diagn. Microbiol. Infect. Dis. 4: 191-201
	23.	Doyle, W.J. (1989) Animal models of otitis media: other pathogens. Pediatr. Infect. Dis J. 8:Suppl. 45-47
	24.	Edebrink, P., et al. (1994) Structural studies of the O-polysaccharide from the lipopolysaccharide of <i>Moraxella (Branhamella) catarrhalis</i> serotype A (strain ATCC 25238). Carbohydr. Res. 257:269-284
	25.	Edebrink, P., et al. (1995) Structural studies of the O-antigen oligosaccharides from two strains of Moraxella catarrhalis serotype C. Carbohydr. Res. 266:237-261
	26.	Edebrink, P., et al. (1996) The structures of oligosaccharides isolated from the lipopolysaccharide of <i>Moraxella catarrhalis</i> serotype B, strain CCUG 3292. Carbohydr. Res. 295: 127-146
	27.	Ejlertsen, T., et al. (1994) Branhamella catarrhalis in children and adults. A study of prevalence, time of colonisation, and association with upper and lower respiratory tract infections. J. Infect. 29:23-31
	28.	Eliasson, I. (1986) Serological identification of Branhamella catarrhalis. Serological evidence for infection. <u>Drugs 31</u> (Suppl. 3):7-10
	29.	Enright, M.C., et al. (1997) Moraxella (Branhamella) catarrhalis-clinical and molecular aspects of a rediscovered pathogen. J. Med. Micro-biol. 46:360-371.
	30.	Erwin, et al. (1991) Enzymatically Deacylated Neisseria Lipopolysaccharide (LPS) Inhibits Murine Splenocyte Mitogenesis Induced by LPS, Infection and Immunity 59(6): 1881-1887
	31.	Faden, H., et al. (1994) Epidemiology of Moraxella catarrhalis in children during the first 2 years of life: relationship to otitis media. J. Infect. Dis. 169:1312-1317
	32.	Fomsgaard, J. S., et al. (1991) Comparative immunochemistry of lipopolysaccharides from Branhamella catarrhalis strains. Infect. Immun. 59:3346-3349
	33.	Fung, C.P., et al. (1992) The antimicrobial susceptibility of <i>Moraxella catarrhalis</i> isolated in England and Scotland in 1991. <u>J. Antimicrob</u> . Chemother. 30:47-55
	34.	Goldblatt, D., et al. (1990) Branhamella catarrhalis: antigenic determinants and the development of the IgG subclass response in childhood. <u>J. Infect. Dis.</u> 162:1128-1135
	35.	Green, B.A., et al. (1994) Nontype <i>Haemophilus influenzae</i> Lipo-oligosaccharide Conjugates as Vaccine Candidates against NTHi, p. 125-129. In E. Norrby. F. Brown, R.M. Chanock, and H.S. Ginsberg (ed), Vaccines 94. Cold Spring Harbor Laboratory Press, Plainview, N.Y.
	36.	Gu, XX et al. (1993) Preparation, Characterization and Immunogenicity of Meningococcal Lipooloigosaccharide-Derived Oligosaccaharide-Protein Conjugates Infect. Immun. 61(5)1873-1880
	37.	Gu, XX., et al. (1995) Quantitation and Biological Properties of Released and Cell-Bound Lipoologosaccharide from Nontypeable Haemophilus influenzae Infect. Immun, 63(10): 4115-4120
	38.	Gu, XX., et al. (1996) Synthesis, characterization, and immunological properties of detoxified lipooligosaccharide from nontypeable <i>Haemophilus</i> influenzae conjugated to proteins. Infect. Immun. 64:4047-4053.
	39.	Gu, XX., et al. (1997) Detoxified lipooligosaccharide from nontypeable <i>Haemophilus influenzae</i> conjugated to proteins confers protection against otitis media in chinchillas. <u>Infect. Immun</u> . 65:4488-4493
	40.	Gu, XX., et al. (1998) Synthesis and Characterization of Lipooligosaccharide-Based Conjugates as Vaccine Candidates for Moraxella (Branhamella) catarrhalis. Infect. Immun. 66:1891-1897
	41.	Gupta, et al. (1992) Synthesis, Characterization, and Some Immunological Properties of Conjugates Composed of the detoxified Lipopolysaccharide of Vibrio cholerae O1 Serotype Inaba Bound to Cholera Toxin. Infection and Immunity 60(8):3201-3208
	42.	Gupta, et al. (1995) Comparative Immunogenicity of Conjugates Composed of Escherichia coli O111 O-Specific Polysaccharide, Prepared by Treatment with Acetic Acid or Hydrazine, Bound to Tetanus Toxoid by Two Synthetic Schemes. Infection and Immunity 63(8):2805-2810
	43.	Helminen, M.E., et al. (1993) A major outer membrane protein of <i>Moraxella catarrhalis</i> is a target for antibodies that enhance pulmonary clearance of the pathogen in an animal mode. Infect. Immun. 61:2003-2010
	44.	Helminen, M.E., et al. (1994) A large, antigenically conserved protein on the surface of <i>Moraxella catarrhalis</i> is a target for protective antibodies. <u>J. Infect. Dis.</u> 170:867-872
	45.	Hochstein, H.D., et al. (1973) Further developments of Limulus amebocyte lysate test. Bull. Paraenter. <u>Drug Assoc</u> . 27:139-148
	46.	Hu, WG., et al. (2000) Enhancement of Clearance of Bacteria from Murine Lungs by Immunization with Detoxified Lipooligosaccharide from Moraxella catarrhalis Conjugated to Proteins. Infect. Immun. 68:4980-4985
	47.	Jennings, H.J., et al. (1984) Conjugation of meningococcal Lipopolysaccharide R-type oligosaccharides to tetanus toxoid as route to a potential vaccine against group B Neisseria meningitidis. Infect. Immun. 43:407-412

EXAMINER	DATE CONSIDERED
*EXAMINER: INITIAL IF CITATION CONSIDERED, WHETHER OR NOT CITATION IN CONFORMANCE AND NOT CONSIDERED, INCLUDE COPY OF THIS FORM WIT	

FORM PTO-1449

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

ATTY. DOCKET NO. NIH142.1CDV1

APPLICATION NO. Unknown

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(USE SEVERAL SHEETS IF NECESSARY)

APPLICANT Gu, et al.

FILING DATE Herewith GROUP Unknown

EXAMINER INITIAL		OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)
	48.	Kelly, J., et al. (1996) Separation and Characterization of O-Deacylated Lipooligosaccharides and Glycans Derived from Moraxella catarrhalis Using Capillary Electrophoresis-electrospray Mass Spectrometry and Tandem Mass Spectrometry. Analy. Biochem. 233:15-30
	49.	Kemp, H.A., et al. (1986) Studies on the deterimental effects of bivalent binding in a microtiter plate ELISA and possible remedies. <u>J. Immunol. Methods</u> 94:65-72
	50.	Konadu, et al. (1994) Preparation, Characterization, and Immunological Properties in Mice of Escherichia coli O157 O-Specific Polysaccharide-Protein Conjugate Vaccines. Infection and Immunology 62(11):5048-5054
	51.	Konadu, et al. (1996) Synthesis, Characterization, and Immunological Properties in Mice of Conjugates Composed of Detoxified Lipopolysaccharide of Salmonella paratyphi A Bound to Tetanus Toxiod, with Emphasis on the Role of O Acetyls. Infection and Immunity 64(7):2709-2715
,	52.	Marrs, C.F., et al. (1990) Pili (fimbriae) of Branhamella species. Am.J.Med. 88(Suppl. 5A):36S-40S
	53.	Masoud, H., et al. (1994) Characterization of the lipopolysaccharide of <i>Moraxella catarrhalis</i> . Structural analysis of the lipid A from M. catarrhalis serotype A lipopolysaccharide. <u>Eur.J. Biochem</u> . 220:209-216
	54.	Masoud, H., et al. (1994) Structural elucidation of the backbone oligosaccharide for the lipopolysaccharide of Moraxella catarrhalis serotype A. Can. J. Chem. 72:1466-1477
	55.	McLeod, D.T., et al., (1986) Increase in bronchopulmonary infection due to Branhamella catarrhalis. Br. Med. J. 292:1103-1105
	56.	Murphy, T.F. (1996) Branhamella catarrhalis: epidemiology, surface antigenic structure, and immune response. Microbiol. Rev. 60:267-279
	57.	Murphy, T.F., et al. (1993) The major heat-modifiable outer membrane protein CD is highly conserved among strains of <i>Branhamella catarrhalis</i> . Mol. Microbiol. 10:87-97
	58.	Nicotra, B., et al. (1986) Branhamella catarrhalis as a lower respiratory tract pathogen in patients with chronic lung disease. Arch. Intern. Med. 146:890-893
	59.	Polotsky, et al. (1994) Comparison of Conjugates Composed of Lipopolysaccharide from Shigella flexneri Type 2a Detoxified by Two Methods and Bound to Tetanus Toxoid. <u>Infection and Immunity</u> 62(1):210-214
	60.	Rahman, M., et al. (1995) Lack of serotype-specific antibody response to lipopolysaccharide antigens of <i>Moraxella catarrhalis</i> during lower respiratory tract infection. <u>Eur. J. Clin. Microbiol. Infect. Dis.</u> 14:297-304
	61.	Rahman, M., et al. (1997) Human immunoglobulin isotype and IgG subclass response to different antigens of Moraxella catarrhalis. APMIS 105:213-220
	62.	Robbins, J.B., et al. (1990) Polysaccharide-protein conjugates: a new generation of vaccines. <u>J.Infect. Dis.</u> 161:821-832
	63.	Robbins, J.B., et al. (1995) Perspective: hypothesis: serum IgG antibody is sufficient to confer protection against infectious diseases by inactivating the inoculum. J.Infect. Dis. 171:1387-1398
	64.	Sarubbi, F.A., et al. (1990) Respiratory infections caused by Branhamella catarrhalis. Selected epidemiologic features. Am. J. Med. 88 Suppl 5A:9S-14S
	65.	Smith, P.K., et al. (1985) Measurement of protein using bicinchoninic acid. Anal. Biochem. 150:76-85
	66.	Svenson, S.B., et al. (1981) Artificial Samonella vaccines: Salmonella typhimurium O-antigen-specific oligosaccharide-protein conjugates elicit protective antibodies in rabbits and mice. <a href="mailto:lnfect.lmmun">lnfect.lmmun</a> . 32:490-496.
	67.	Tsai, C.M., et al. (1982) A sensitive silver stain for detecting lipopolysaccharides in polyacrylamide gels. Anal Biochem. 119:155-119
	68.	Vaneechoutee, M., et al. (1990) Respiratory tract carrier rates of <i>Moraxella (Branhamella) catarrhalis</i> in adults and children and interpretation of the isolation of M. catarrhalis from sputum. <u>J. Clin. Microbiol.</u> 28:2674-2680
	<b>6</b> 9.	Vaneechoutee, M., et al. (1990) Serological Typing of Branhamella catarrhalis strains on the basis of lipopolysaccharide antigens. <u>J. Clin. Microbiol</u> . 28:182-187
	70.	Verheul, A.F.M., et al. (1991) Preparation, characterization, and immunogenicity of meningococcal immunotype L2 and L3,7,9, phosphoethanolamide group-containing oligosaccharide-protein conjugates. <u>Infect.Immun</u> . 59:843-851
	71.	W.H.O. Expert Committee on Biological Standardization (1991) Requirements for <i>Haemophilus</i> type b conjugate vaccines. WHO Tech. Rep. Ser. 814:15-37
	72.	Wagner, D.K., et al. (1987) Analysis of immunoglobulin G antibody responses after administration of live and inactively influenza A vaccine indicates that nasal wash immunoglobulin G is a transudate from serum. J. Clin. Microbiol. 25:559-562
	73.	Yang, Y.P., et al. (1997) The major outer membrane protein, CD, extracted from Moraxella (Branhamella) catarrhalis is a potential vaccine antigen that induces bactericidal antibodies. <u>FEMS Immunol. Med. Microbiol</u> . 17:187-199
	74.	Zollinger, W.D., et al. (1983) Importance of complement source in bactericidal activity of human and murine monoclonal antibody to meningococcal group B polysaccharide. Infect. Immun. 40:257-264

EXAMINER	DATE CONSIDERED
*EYAMINED: INITIAL IS CITATION CONSIDERED WHETHER OR NOT CITATION I	S IN CONFORMANCE WITH MORE 600: DRAW LINE THROUGH CITATION IF NOT

\*EXAMINER: INITIAL IF CITATION CONSIDERED, WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP 609; DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED, INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT.

SHEET 4 OF 4

FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. NIH142.1CDV1	APPLICATION NO. Unknown
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	APPLICANT Gu, et al.	
(USE SEVERAL SHEETS IF NECESSARY)	FILING DATE Herewith	GROUP Unknown

O:\DOC\$\NWV\NWV-9308.DOC 112503

EXAMINER	DATE CONSIDERED
<b>1</b>	